

### **REMARKS**

Reconsideration of the present application, as amended, is respectfully requested.

Since the present response raises no new issues for consideration and, in any event, places the present application in better condition for consideration on appeal, it is respectfully requested that this amendment be entered in response to the Final Office Action and Advisory Action dated July 30, 2003.

It is noted that a Notice of Appeal was transmitted to the USPTO via First Class mail on June 3, 2003 and received in the USPTO on June 6, 2003. This response is being transmitted with a petition for a one month extension of time which extends the deadline for filing the response up to and including September 6, 2003.

The undersign wishes to thank the Examiner for the courtesies extended during the telephone interview conducted September 3, 2003. It is urged that the amendments submitted herewith are the same as that discussed with the Examiner and included as part of the first Rule 116 Amendment which was not entered by the Examiner.

#### **A. STATUS OF THE CLAIMS**

As a result of the present amendment, claims 1-32 are presented in the case for continued prosecution. It is noted that new claim 32 was necessitated in view of the amendment made to claim 1. The subject matter was originally presented in claim 4 of the application. No new matter has been added and no new search is required.

#### **B. TERMINAL DISCLAIMER Re USSN 09/823,296**

A terminal disclaimer was transmitted with the first Rule 116 Amendment and has been entered by the Examiner. If necessary, Applicants will re-transmit a copy of the same to the Examiner.

#### **C. REJECTIONS UNDER 35 U.S.C. § 102**

Claims 1-15, 17-20 and 23-31 Are Not Anticipated By U.S. Patent No. 5,620,689

At page 3 of the Office Action, the Examiner has repeated the rejection of the subject matter of the above mentioned claims under 35 U.S.C. '102(b), as being anticipated by U.S. Patent No. 5,620,689 (hereinafter the '689 patent). In response, Applicants have amended the

claims to further define the invention and distinguish over the reference. Specifically, as pointed out in the first telephone interview, the independent claims have been amended to require the presence of the spacer moiety as part of the claimed compounds, by virtue of the fact that  $e$ ,  $f$  and  $g$  must now be positive integers. This element is not described in the '689 patent. Therefore the pending claims are not anticipated by the cited reference. In addition, there is no disclosure or suggestion to add the spacer groups claimed herein. As pointed out in the paragraph bridging pages 5 and 6 of the specification, the extenders between the polymer residue ends and the parent therapeutic molecules have several advantages over the prior art. For example, they allow the polymer-based prodrugs to have a more predictable degree of loading. The substantially uniform polymeric conjugates are thus easy to analyze and are highly reproducible. The rate of hydrolysis is also predictable and reproducible from batch to batch. In view of the foregoing, it is respectfully urged that the Examiner reconsider and remove the rejection and pass the application to allowance.

**D. ADVISORY ACTION**

As was discussed during the telephone interview conducted September 3, 2003, the Advisory Action of July 30, 2003 indicated that the first Rule 116 Amendment would not place the application in condition for allowance. The Examiner cited figure 3B of the '689 patent and compound number XXXII as still reading on the claimed invention. In response thereto, Applicants urge that compound XXXII does not anticipate the invention as currently claimed. Specifically, as pointed out in the interview, the claims require G to be a straight or branched polymer residue while the '689 patent teaches that a lipid, specifically DSPE should be employed. Since a lipid not the same as the polymer required by the claims, it cannot be said that the claims are anticipated by compound XXXII of the '689 patent or any other portion thereof. Entry of the Amendment is therefore proper and earnestly solicited.

**E. FEES**

This response is being filed during the time allowed for filing an Appeal Brief. Applicants previously submitted a Notice of Appeal which was received by the USPTO on June 6, 2003. Therefore, the petition for one month extension of time included herewith extends the pendency of this application until September 6, 2003. No further fee is required. If, on the other

hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275.

**F. CONCLUSION**

In view of the actions taken and arguments presented, it is respectfully submitted that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

MUSERLIAN, LUCAS & MERCANTI, LLP

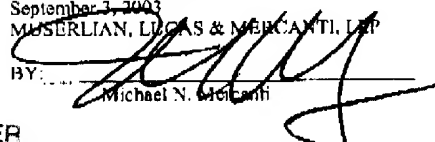
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CERTIFICATE OF FACSIMILE TRANSMISSION I hereby certify that this Response is being facsimile transmitted to the Commissioner for Patents on September 3, 2003 MUSERLIAN, LUCAS & MERCANTI, LLP BY:  Michael N. Mercanti
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